Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH), (http://www.nih.gov/)

Components of Participating Organizations
This RFA is developed as an NIH Roadmap initiative (http://nihroadmap.nih.gov). All NIH Institutes and Centers participate in Roadmap initiatives. The RFA will be administered by the National Institute of Child Health and Human Development (NICHD) (http://www.nichd.nih.gov/) on behalf of the NIH.

Title: Multidisciplinary Clinical Research Career Development Programs

Announcement Type
Reissue of RFA-RM-04-006, released October 20, 2003.

Request For Applications (RFA) Number: RFA-RM-05-016

Catalog of Federal Domestic Assistance Number(s)
93.865

Key Dates
Release Date: January 4, 2005
Letters Of Intent Receipt Date(s): February 25, 2005
Application Receipt Dates(s): March 25, 2005
Peer Review Date(s): June/July 2005
Council Review Date(s): September 2005
Earliest Anticipated Start Date: September 30, 2005
Additional Information To Be Available Date: December 29, 2004
Additional information will be available at the program web site (http://www.nichd.nih.gov/RFA/HD-04-006/roadmap.htm) and Listserve (http://list.nih.gov/archives/clinrescareers.html).
Expiration Date: March 26, 2005

Due Dates for E.O. 12372
Not Applicable.

Additional Overview Content

Executive Summary

- **Purpose:** The purpose of this RFA is to support the early career development of clinical researchers who would be expected to achieve excellence in their ability to design and oversee research in multidisciplinary team settings, and have a high potential to become leaders of various fields of clinical research critical to the overall mission of the National Institutes of Health (NIH). To accomplish this aim, the NIH invites institutions with well-established clinical research infrastructures to submit applications for the establishment of Multidisciplinary Clinical Research Career Development Programs. Career Development Programs supported under this RFA must include a broad representation of clinically relevant disciplines and professions (including but not limited to internal medicine, surgery, pediatrics, obstetrics/gynecology, dentistry, nursing, pharmacy, statistics, nursing, psychology, and engineering) and their various specialties and sub-specialties. Programs must include a structured core didactic component and a practical training component in various aspects of the design,

conduct, and analysis of clinical research. Individuals should be trained in team research settings and will be known as NIH Clinical Research Scholars (CR Scholars).

- **Funds Available:** The NIH Roadmap plans to provide approximately $4 million for this initiative in FY 2005.
- **Size and Duration of Awards:** Individual awards may be up to $950,000 direct costs for the first year, then escalate to up to $2.05 million direct costs in the second year, and up to $3.37 million direct costs in the third through fifth years.
- **Mechanism of Support:** The Mentored Clinical Scientist Development Program Award (K12) mechanism.
- **Eligible Organizations:** For-profit or non-profit public or private institutions, such as universities, colleges, and hospitals. Foreign institutions are not eligible to apply.
- **Eligible Principal Investigators** should have a strong and active track record in clinical research, clinical research training, and administration that demonstrates the skills, knowledge, and experience necessary to develop and manage the proposed Career Development Program.
- **Number of applications each eligible institution may submit:** One
- **Where one can get application materials:** Applications must be prepared using the PHS 398 forms. The PHS 398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301)435-0714, Email: GrantsInfo@nih.gov.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Background

The National Institutes of Health (NIH), in keeping with its mission, is engaged in a series of initiatives collectively known as the “NIH Roadmap” (http://nihroadmap.nih.gov/), the goal of which is to accelerate both the pace of discovery of new knowledge in the prevention, detection, diagnosis, and treatment of disease and the translation of these discoveries into applications that will improve the health of the nation. The objective of this initiative is to enhance the career development and training of postdoctoral and junior faculty health professionals in multidisciplinary, team research settings for leadership roles in the design and oversight of future clinical investigation. The overarching goal is to promote clinical investigation that will have a significant impact on improving health and preventing disease.

For the purpose of this initiative, “clinical research” refers to all aspects and kinds of clinical research including, for example, epidemiologic and natural history studies, translational research, patient-oriented research, clinical trials, and outcomes research.

Clinical research embraces a spectrum of scientific disciplines (medicine, surgery, dentistry, nursing, pharmacology, statistics, psychology, engineering) that are employed by health professionals, often in specialties and sub-specialties (e.g., internal medicine, surgery, pediatrics, obstetrics/gynecology, oncology, cardiology, nephrology, and others) using a variety of study methodologies (e.g., epidemiology, observational, experimental, and others). Clinical research is a complex endeavor that is ideally performed by a multidisciplinary team using an integrated team approach. A multidisciplinary approach brings experts from diverse disciplines (for example, clinician, clinical researcher, clinical trialist, statistician, medicinal chemist, and pharmacologist) to address collectively a common complex problem. There is a well-recognized shortage of well-trained physicians and other health professionals (e.g., dentists, behavioral scientists, clinical pharmacologists, statisticians, nurses, study coordinators, and data managers) performing clinical research in a rigorous, highly collaborative, team-oriented environment.

This initiative will support the development and implementation of integrated Multidisciplinary Clinical Research Career Development Programs (referred to as Program in the following) that provide CR Scholars with knowledge and skills of the discipline of clinical research that are applicable to all diseases and organ systems. Programs should be designed to provide a flexible and efficient entrance into clinical research for doctoral-level individuals with a variety of disciplinary, specialty, or sub-specialty backgrounds, should emphasize the development of the entire clinical research team, and should reflect the prolonged time to develop and support the development of competent and independent clinical researchers. By providing this career development experience in a multidisciplinary setting, it is hoped that

those completing the Program will be better prepared for the multidisciplinary real world requirements of clinical research.

Specific Objectives

The objectives of these new Career Development Programs are: (1) to stimulate and accelerate collaborative, multidisciplinary clinical research training and education; (2) to enhance the career development and training of scientists with doctoral-level professional degrees, who represent a broad range of disciplines, professions, specialties and sub-specialties and who can develop into the future leaders in all areas of clinical research; and (3) to establish a critical mass of national Programs devoted to developing an integrated, multidisciplinary, and diverse workforce that will meet the current and future clinical research needs of the nation.

Individuals will be trained in team research settings. Programs will include didactic and practical training in various aspects of the design, conduct, and analysis of clinical research with the goal of advancing clinical research in complex areas of medicine and promoting the conduct of research in highly collaborative settings. Programs must develop and propose a core didactic curriculum that will be presented to all first-year CR Scholars. Examples of a multidisciplinary core curriculum include:

- Clinical research methodology (including hypothesis generation, protocol design, etc.)
- Epidemiology
- Biostatistics
- Informatics
- Ethical issues in clinical trials (e.g., informed consent)
- Ensuring the safety of subjects in clinical trials
- Compliance with regulatory requirements for clinical research
- Team building, leadership and management skills
- Strategic, tactical, and negotiation skills
- Grant writing and career development
- Interactions with industry

Scope

The first year of each CR Scholar's program should be dedicated primarily to core curriculum that must include a multi-disciplinary aspect to foster interactions among CR Scholars and faculty from various disciplines. The curriculum should link to other available clinical research training programs at the institutions, such as a K30 program, a General Clinical Research Center program, or individual research fellowship programs supported by the NIH. The Program must demonstrate the flexibility to accommodate multiple disciplines and CR Scholars with different levels of education, training, and didactic and research experience. CR Scholars may obtain a certificate or degree upon completion of the Program (see below).

The second through (up to) fifth year of each CR Scholar's program should consist of: (1) a “hands-on” research experience (e.g., protocol development, data analysis planning, preparation of IRB applications, clinical research/trial management including patient accrual, data analysis, and report writing) in an existing team clinical research setting available at the institution, and (2) developing a clinical research project to provide experience in grant writing and project management.

While the institution is expected to have sufficient ongoing clinical research projects to fulfill this requirement, it may lack specific shared clinical research support elements. Therefore, Programs may ask for funding to develop additional shared clinical research support facilities critical to the conduct of team research, including, for example, specialized expertise in clinical research design and/or statistics, or a pool of study coordinators (see below) to be used by the CR Scholars.

The programs are expected to be scholar-based, serve a National need by sharing resources with other institutions, and not designed to satisfy the needs of a single institution. This is a reissue of a previous RFA (http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-006.html) ; the two cohorts of Programs will work together to form a National program.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the NIH Mentored Clinical Scientist Development Program (K12) award mechanism (s). As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses the just-in-time budget concepts. It also uses the non-modular budget format described in the PHS 398 application instructions (see http://grants.nih.gov/grants/funding/phs398/phs398.html). A detailed categorical budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" is to be submitted with the application.

2. Funds Available

The NIH intends to commit approximately $4 million in total costs [Direct plus Facilities and Administrative (F&A) costs] in FY 2005 to fund four to five new and/or competing continuation grants in response to this RFA. An applicant may request a project period of up to five years.

In the first year of the award, an applicant may request up to $950,000 direct costs. These funds would support an initial six-month planning/recruitment phase for up to $250,000 direct costs and up to $700,000 direct costs to support the training of approximately five to eight CR Scholars. The second portion (up to $700,000) will be restricted until the receipt and successful administrative review of the six-month progress report; the restricted funds will then be made available for expenditure. Notice of Grant Awards will be issued no later than September 30, 2005.

For the second year, applicants may request up to $2.05 million in direct costs, which is intended to support a total of approximately 11-14 CR Scholars. For the third year, applicants may request up to $3.37 million in direct costs, which is intended to support a total of approximately 18-23 CR Scholars. Subsequent yearly awards may be requested for up to $3.37 million in direct costs, which are intended to support a total of approximately 18-23 CR Scholars. F & A costs for these awards are limited to eight percent of modified total direct costs. Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation (see NOT-OD-04-040).

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the NIH provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State government
- Units of local government
- Domestic Institutions/organizations
- Foreign Institutions are not eligible to apply

An eligible institution (e.g., university) may submit only a single application in response to this RFA, and may not have received a previous NIH Roadmap K12 award. Multiple applications from different divisions, faculties, centers, schools, etc. at the same university will be returned without further consideration by the NIH.

Applicant institutions must have strong clinical research faculty representing a broad spectrum of clinical disciplines, specialties, and sub-specialties; sufficient ongoing clinical research projects to serve as the platform for active participation of CR Scholars; extensive clinical research facilities; and a strong track record of competing for clinical research support to meet the purposes of this Program, namely, to encourage/enhance clinical research training and career development that promotes health and prevents disease. Collaborating institutions may be included to supplement training activities in needed areas.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

The Program Director will be responsible for planning, directing, and executing the proposed Career Development Program for the institution. Program Directors must be senior faculty members or Directors of Research Centers or Multidisciplinary Institutes, and have a strong and active track record in clinical research, clinical research training, and administration that demonstrates the skills, knowledge, and experience necessary to develop and manage the proposed Career Development Program.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the most current Grants Policy Statement, which can be found at: http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_Part2.htm#matching_or_cost_sharing.

3. Other-Special Eligibility Criteria

Clinical Research Scholar (CR Scholar) Candidates: CR Scholar positions are open to health professionals with doctoral-level degrees, but distinct from clinical fellowships with specific requirements leading to clinical certification. Candidates for support as CR Scholars must: (1) be US citizens or non-citizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-155) or some other verification of legal admission as a permanent resident. Individuals on temporary or student visas are not eligible; (2) have a clinical doctorate or Ph.D. degree or its equivalent; (3) be able to commit at least 50-75 percent of full-time professional effort in this Career Development Program and its related clinical research activities; (4) have identified a mentor with extensive clinical research experience; (5) not be or have been a Principal Investigator on an R01, R29, or subproject of a Program Project (P01), Center (P50, P60, U54), mentored career development (K-series) grants, or other equivalent research grant awards, except for R03 and R21.

Clinical doctorate degrees include, but are not limited to, the M.D., D.P.H., D.O., D.D.S., D.M.D., D.V.M., O.D., D.C., Pharm.D., N.D.(Doctor of Naturopathy), Ph.D., Sc.D., as well as epidemiologists, behavioral scientists, and nurses with doctoral degrees.

The K12 award will provide for a minimum of two years and a maximum of five years of consecutive funding for each CR Scholar, consisting of consecutive 12-month appointments. In general, 75 percent of the CR Scholars' full-time professional effort must be devoted to the K12 Program. However, certain clinical specialties can have less than 75 percent, but no less than 50 percent, protected time for this Program if sufficiently justified (for example, surgical specialties requiring 50 percent direct patient care time to keep up surgical skills).

CR Scholars may receive a certificate of completion or an advanced degree (if applicable). CR Scholars are encouraged to apply to the NIH Loan Repayment Program (http://www.lrp.nih.gov).

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 398 application instructions are available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at http://www.dnb.com/us/. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

See also Section VI.2. for additional information.

Content of the Application

The NIH recognizes that individual institutions will be positioned to respond in different ways to the opportunities presented in this RFA. However, all Programs are expected to provide multidisciplinary clinical research career development experiences for the CR Scholars. Applicants must address the following specific program elements:

1. Overall Approach: Career Development Programs must have a strong and broad base of on-going clinical research. The Program must offer clinical research training that crosses at least four disciplines (for example, clinical research design, epidemiology, statistics, pharmacology, informatics, behavioral science, and engineering) across a wide range of health professions (medicine, surgery, dentistry, nursing, pharmacology). The Program must include two phases: (1) a didactic clinical research education component, and (2) a practicum phase in which clinical research is performed under the guidance of a qualified mentor or mentors. Although the first phase will address general core issues, the practicum will be tailored to the background and interests of the CR Scholar. The focus of the Program must not be restricted to a single problem, but rather should be dispersed across multiple health conditions and not be restricted to a single disease or health problem (e.g., cardiovascular disease, cancer, diabetes, etc.).

During the practicum phase, we expect that an individual CR Scholar's research projects may be focused on a single disease or health problem. The Program phases are described in more detail below. The intent is to provide didactic training before the practicum, but the phases might overlap if sufficient justification is provided.

The Program should have a broad focus and representation from multiple disciplines and specialties. The CR Scholars, Advisory Panel Members, and Mentors should come from a diverse range of disciplines, specialty, and sub-specialty areas. Each yearly class should include CR Scholars whose backgrounds span at least two to three disciplines, specialty, and sub-specialty areas. When fully implemented, the Program should have CR Scholars in at least four disciplines.

A CR Scholar Ombudsman may be included to, for example, provide unbiased help to the CR Scholars, and shepherd them through the program.

2. Program Director: The Program Director must be a senior faculty member or Director of a research center or multidisciplinary institute, who possesses the scientific background, leadership, and administrative capabilities required to coordinate and supervise a multidisciplinary clinical Research Career Development Program of this scope. The application may include co-director(s) from the same institution or from partnering or collaborating institutions. These co-director(s) should be experienced investigators who have administrative skills and backgrounds that complement those of the PI.

3. Multidisciplinary Advisory Committee (MAC): The Program Director must appoint and chair a permanent

Multidisciplinary Advisory Committee. The MAC would be responsible for recruiting and selecting CR Scholars to the Program; establishing and reviewing the core curriculum; approving the education and career development plans (e.g., curriculum, mentors, research experience) and customizing an individual career development program for each CR Scholar; providing interim monitoring and evaluation of each CR Scholar's progress with recommendations for modifications in the plan, if necessary, or termination of a CR Scholar who is not making adequate progress; and monitoring and evaluating the overall effectiveness of the Program. The MAC may set criteria to award graduates of the Program a certificate of completion. The MAC should meet regularly and keep written minutes, which may be reviewed as part of an NIH site visit, or in review of a competing or non-competing continuation application. The MAC would provide a summary annual progress report of the Program's development, including an evaluation of areas of strengths and weaknesses.

The MAC or a subgroup of the MAC, which can be supplemented with additional expertise either from within or outside of the institution, will also be responsible for conducting the peer review of clinical research projects submitted by the CR Scholars during the final stage of their Practicum Phase/Mentored Research Experience. The purpose of these projects will be to introduce the CR Scholars to the planning and preparation of a research project, to allow the CR Scholar to make revisions of the project in response to peer review, and to allow the CR Scholar to develop preliminary results that can form the basis for an independent research program. Projects supported from this grant are expected to comply fully with all Federal policies, rules, and guidelines applicable to research involving human subjects and animals.

4. Mentors: Each CR Scholar appointed under the K12 award must be supervised by a mentoring team of at least two mentors from different disciplines or specialties (for example, one clinical/translational and the other basic science; or a sub-specialist clinical researcher and a clinical trialist). The primary mentor should be recognized as an independent investigator and be actively involved in clinical research, and demonstrate a successful track record of mentoring and providing research training and career development of a type expected in this Program. The mentors must be committed to continue this involvement with the CR Scholar for the duration of his/her appointment on this Career Development Program. Each program should have a representative sample of mentors, at least 25.

5. Clinical Research Capability and Infrastructure: The institution must demonstrate that it has a broadly funded clinical research base, the infrastructure to support clinical research (for example, GCRC, biostatistics expertise, etc.), and the facilities (e.g., inpatient and outpatient facilities, affiliate hospitals, etc.) and patient resources to address multiple diseases and health conditions.

6. Planning Phase: All Programs must propose a six-month Planning Phase in a special section of the application with clear, quantifiable targets or milestones for establishing management procedures, developing and implementing required infrastructure necessary to complement existing infrastructure needed for the Program, integrating all infrastructure of the Program so it works in a unified manner, and initiating recruitment plans for bringing CR Scholars into the Program. Completion of the Planning Phase (i.e., reaching the proposed milestones) will result in the release of restricted funds for the first five to eight CR Scholars who will begin their training in the first year of the Program.

7. Didactic Clinical Research Curriculum: Each CR Scholar must first receive didactic training in an extensive core curriculum that should include, for example, course work in epidemiology, behavioral science, study design, statistics, regulatory compliance, bioethics, responsible conduct of research, mentoring, leadership and team building skills. These courses should be designed to be taken by the entire multidisciplinary group of CR Scholars. The curriculum can be individualized, depending upon the level of experience of the CR Scholar. For example, CR Scholars with sufficient expertise that is well documented in a specific area (e.g., statistics) may be exempted from that aspect of the core curriculum by demonstrating mastery of that area. In addition, some candidates may need to receive concurrent or simultaneous didactic training and a mentored research practicum experience.

In addition, Programs should propose career development opportunities such as regular journal clubs, seminars, grand rounds, and other forums designed specifically for CR scholars. These should facilitate the exchange of ideas, collaboration among scholars, and networking opportunities among CR scholars, mentors, and the Program Director.

Programs are encouraged to be family friendly and to use senior or alumni CR Scholars to train junior CR scholars. Also, courses may be offered for the training of mentors in mentoring, leadership, management, and team building.

8. Practicum Phase/Mentored Research Experience: The mentored/team research experience must last a minimum of one year. Each CR Scholar should be supervised by a mentoring team of at least two mentors from different disciplines or specialties (for example, one clinical/translational and the other basic science; or a sub-specialist clinical researcher and a clinical trialist). The primary mentor should be recognized as an independent investigator and be actively involved in clinical and/or translational research, and demonstrate a successful record of mentoring and

providing research training and career development of a type expected in this Program. The mentors must be committed to continue this involvement with the CR Scholar for the duration of his/her appointment on this Career Development Program. This practicum phase may be divided into two parts:

a) Participation in an ongoing clinical research project. The CR Scholar will be an active team member, working alongside the mentor/team lead.

b) Development and implementation of a new research project by the CR Scholar under the guidance of a mentor(s). The CR Scholar will write a research proposal, which will be reviewed and approved by the MAC. It is expected that the project will receive ongoing support by the Shared Research Support Facility (described below) and sufficient oversight by the primary mentor. The K12 application should describe the process and review criteria, including the application, review, oversight, and evaluation procedures, and adherence to all Federal rules and guidelines regarding clinical research.

9. Shared Clinical Research Support Facility: The applicant should provide evidence of existing specialized shared clinical research support facilities that aid CR Scholars in developing and managing their research projects. The applicants should also provide a gap analysis to indicate what infrastructure resources are needed, and a plan for acquiring and implementing them. With strong justification, a Shared Clinical Research Support Facility may be requested as part of the Career Development Program, within the total Budget Request. The Facility may include, for example, a research design incubator with statistical expertise, a shared pool of study coordinators to work with the CR Scholars, or a module for curriculum development and evaluation. The Shared Clinical Research Support Facility must be a separate entity, not an extension or enhancement of an individual investigator's laboratory. The design of the new shared facility will be influenced by the type of research conducted at the institution and will build upon the specific strengths of existing programs (e.g., K30 and GCRC programs, program project and Center grants, or similar elements).

10. Institutional Commitment: Applicant institutions should show commitment to the Program's goals, and provide assurances that the institution intends the Program to be an integral part of its research endeavor. Research facilities and training opportunities will be a critical part of the environment. Institutional commitment in support of the proposal must be obtained by letters from high-ranking institutional officials that: (1) describe how the proposed Program will be an integral component of the institution's broader vision with respect to clinical research; (2) outline how institutional barriers for clinical research and clinical researchers will be or are being addressed (i.e., promotion and tenure, etc.); and (3) provide a guarantee of 75 percent protected time (or at least 50 percent in certain cases) for the CR Scholars. The letters should supply evidence of an active clinical research faculty, statistical and epidemiologic support, basic science support for clinical research questions, and associations with schools of medicine and/or public health, departments of behavioral and/or social sciences, and other resources. Include the specifics of institutional support. There is no dollar requirement, but significant commitment, be it financial support or dedicated space, will be considered a strength in the review of these applications. Co-funding or matching funds from other sources (including industry) are encouraged, as long as these funds do not limit scholars' choices at any point and there are methods in place to ensure transparency and to prevent misuse of federal funds.

11. Integration with Other Related Institutional Programs: Interaction and overlap with existing local clinical research training infrastructure (Schools of Public Health, departments, K30 awards, etc.) should be identified and clarified, and integrated into a single, unified institutional Program. Applications should also describe interactions with GCRCs and existing disease-focused NIH-funded Centers and other clinical research programs (Program Project grants, Center grants, Foundation-sponsored Centers, etc.).

12. Innovation: Programs with novel concepts, methodologies, and approaches to providing the skill sets essentials for the conduct of clinical research education will be considered a strength. In addition, institutions with other K12 programs must provide strong evidence that the addition of this K12 will provide clinical research career development and mentoring that is distinct from existing K12 programs, including avoidance of overlap in research topics.

13. Evaluation and Tracking Component: The applicant should describe a strong evaluation and tracking component, that will review the effectiveness of all aspects of the Program (including scholars, courses, mentors, MAC members, PI, as well as institutional characteristics), and a system for tracking graduates throughout their career to determine the success rate of applying for and obtaining Federal and non-Federal research grant support. This should include enrollment and appointment information (diversity of backgrounds, disciplines, and specialties) and outcomes measures (academic placement, clinical vs. basic science research), etc. In addition to the measures that focus on scholars, the applicant will be expected to collect data that measures institutional factors (multidisciplinary research efforts, research infrastructure integration, etc.) during the period of the award.

14. Recruitment Plan: Applicants must submit a recruitment plan that includes a scheme for: (1) recruiting CR Scholars from both outside and inside their institution(s), and (2) recruiting under-served and under-represented minority and ethnic populations.

The success of efforts to recruit and retain individuals in underrepresented population groups is a factor in the assessment of the quality of the scholar pool. The review panel's evaluation will be included in an administrative note in the summary statement. If the plan or the record of minority recruitment and retention is judged to be unacceptable, funding will be withheld until a revised plan (and report) that addresses the deficiencies is received. NIH Staff will determine whether amended plans and reports submitted after the initial review are acceptable.

Collaboration with less research-intensive institutions or minority institutions will be viewed as a strength.

15. Participation in a National Program: Programs will be expected to interact extensively with the NIH and other Multidisciplinary Clinical Research Career Development Programs, and be part of a National Clinical Research Career Development effort that is part of NIH's Roadmap Program to Re-engineer the Clinical Research Enterprise. The NIH will facilitate communication among the Program Directors via phone calls, a Listserve, and a Program website (http://www.nichd.nih.gov/RFA/HD-04-006/roadmap.htm). NIH will host a planning meeting within the first month of the Program. Attendance at an annual meeting of the Program Directors and CR Scholars with the NIH staff will be required for the purpose of sharing information, having a discussion of evaluation efforts and making midcourse corrections that will improve Programs. NIH Program Staff will conduct periodic site visits, will review each site's progress in meeting its overall goals, and provide financial oversight of the Program.

Proposed CR Scholars will be selected by the MAC, with review and final approval by NIH Program Staff. The Program Director will be required to submit appointment forms for each CR Scholar to the NIH. Applicants must notify NIH if there is a change in PI, co-PI, or a CR Scholar's mentor.

16. Responsible Conduct of Research: Applications must include plans for instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency, and duration of instruction, and the amount and nature of faculty participation. No award will be made if an application lacks this component.

Form of the Application

The instructions in the Form PHS 398 do not fully apply to the special needs of this grant application. Therefore, follow the modified instructions below in preparing an application for a Multidisciplinary Clinical Research Career Development Program (K12). These instructions have been adapted to accommodate the PHS 398 and the special needs of the K12 grant:

1. Face Page: Use Form Page 1 of the PHS 398. On Line 1, include the title that best represents the nature of the Career Development Program. On Line 2, provide the number of this Request for Applications, RFA-RM-05-016, and the RFA title "Multidisciplinary Clinical Research Career Development Programs." The Program Director will be the Principal Investigator (PI) of the grant application.

2. Description/Performance Site(s)/Key personnel (Form Page 2 of PHS 398): Complete as directed in the PHS 398 instructions. The information provided should include the PI, Advisory Committee members, mentors, and other faculty participating in the Program.

3. The application should be organized as follows (when following this format, applicants should refer regularly to those sections of this announcement that delineate “special programmatic requirements” and “review criteria”):

A. Face Page

B. Description, Performance Sites, and Key Personnel

C. Table of Contents

D. Detailed Budget Page for Initial Budget Period: Three sets of budget pages are required. The first set is for the first six months (i.e., Planning Phase), and the second set is for the second six months (i.e., initial implementation phase for five to eight CR Scholars). The Scholar support, mentor support, and Research Project support should be prorated for six months.

E. Budget for Entire Proposed Period of Support that escalates the number of scholars to 11-14 in the second year and to 18-23 in the third, fourth, and fifth years

F. Biographical Sketches in standard NIH format for Program Director, co-director(s), Multidisciplinary Advisory Committee (MAC) members, Mentors, and Other Faculty of this Program

G. Other Support: for the Program Director, Co-director(s), MAC members, Mentors, Other Faculty of this Program

H. Multidisciplinary Clinical Research Career Development Program (no more than 60 pages): The application must present the proposed program in up to 60 pages. Applicants are strongly discouraged from giving programmatic URL's in their applications, and reviewers are not obligated to view applicant's web sites to review existing public information. The information should be arranged as follows:

(1) Overall Aims

- Approach/Meeting the Intent of this Initiative
- Institutional Commitment
- Innovation
- Collaboration

(2) Major Program Elements

- Clinical Research Capability and Infrastructure: Include a description and use of the suggested tables and plans if any for a Shared Clinical Research Support Facility
- Program Leadership/Management
- Multidisciplinary Advisory Committee: Include plans for matching CR scholar to mentor; include policies and procedures for the Research Project Support Program
- Program Mentors/Team Leaders
- Description of Didactic Core Requirements and Practicum research experience
- Interactions

(3) Candidate Pool and Recruitment Plans

(4) Evaluation/Tracking

(5) Planning phase and milestones

I. Human Subjects

J. Vertebrate Animals

K. Checklist

L. Tables: Suggested tabular formats to supplement not replace the narrative section. These tables will help reviewers to assess ongoing clinical research infrastructure at your institution. PLEASE INCLUDE TABLES IN THE BODY OF THE GRANT APPLICATION. No appendices are allowed. More information about the suggested format of these tables will be available at the K12 Roadmap program web site (http://www.nichd.nih.gov/RFA/HD-04-006/roadmap.htm).

- Funded Training and Career Development Programs Relevant to Clinical Research. This table should include all programs within the institution that are relevant to the purpose and objectives of the Program (e.g., K30s, T32s, R25s, K12s, GCRCs, School of Public Health, Degree Programs, etc.). The table should be organized by the following headings: Principal Investigator, Source of Support (e.g., Institution, NIH, Other Federal agencies, non-federal support, Industry), number of scholars, and description (no more than two sentences).

- Existing Funded Clinical Research Support. This table should include a representative sample (up to 25 studies) of the clinical research currently being conducted in the Institution(s).

- Clinical Research Infrastructure. This table should include all shared clinical research facilities within the institution(s) (e.g., GCRCs, incubators, statistical expertise, etc.).

- Expertise and Training Track Record of Program Director, Co-directors(s), MAC and Mentors. This list should include a representative sample of mentors (at least 25 but not more than 40). For each person, please include a list of 5-10 recent trainees, in the past 10 years (Trainee Name, degree, research project, current position, current research area if known).

3. Submission Dates and Times

Applications must be received on or before the receipt date described below (Section IV.3.A). Submission times not applicable.

3.A. Receipt, Review and Anticipated Start Dates

Letters Of Intent Receipt Date(s): February 25, 2005
Application Receipt Dates(s): March 25, 2005
Peer Review Date(s): June/July 2005
Council Review Date(s): September 2005
Earliest Anticipated Start Date: September 30, 2005

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document.

The letter of intent should be sent to:

Joan Davis, M.D., M.P.H.
Program Director, Multidisciplinary Research Programs
Center for Population Research
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8B01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-6515
E-mail: jd372m@nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Robert Stretch, Ph.D.
Director, Division of Scientific Review
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 5B01, MSC 7510
Bethesda, MD 20892-7510
Rockville, MD 20852 (for express/courier service; non-USPS service)

Using the RFA Label: The RFA label available in the PHS 398 application instructions must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/labels.pdf. Personal deliveries of applications are no longer permitted.

3.C. Application Processing

Applications must be **received on or before the application receipt date(s)** described above (Section IV.3.A.). If an application is received after that date, it will be returned to the applicant without review. Upon receipt, applications will be evaluated for completeness by the CSR and responsiveness by the NICHD. Incomplete and non-responsive applications will not be reviewed.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm (see also Section VI.3. Reporting).

Allowable Costs

1. Salary: The NIH will provide salary and fringe benefits for each CR Scholar position for 50-75 percent of their effort for a minimum of two years and a maximum of five years. The total 12-month salary from this grant may be up to the NIH legislative cap, although the institution may supplement from non-Federal sources. The total salary requested must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

2. Personnel Costs for Program Director and Mentors: The program director may request between 20 percent and 40 percent effort to organize and run the program. In general, higher levels of effort are expected in the first two years of the program (during program set up) and lower levels in the later years. Mentors may be paid up to $5,000 per year (up to two mentors per CR Scholar). Salary for faculty to develop and implement needed core clinical research curricula and training modules may be included.

Salary for an administrative assistant may be included at 0.5 to a maximum of 1.0 FTE in the first year, 0.75 to a maximum of 1.25 FTE in Year 2 and 1.0 to a maximum of 1.5 FTE in the third through fifth year of the award.

3. Other Expenses: The K12 may be used toward the following expenses: (1) Travel for Program Director and co-director (if applicable) to the initial meeting in October 2005; (2) tuition, fees, and books related to career development; (3) travel for Program Director, co-director (if applicable), and CR Scholars to the annual NIH meeting for CR Scholars; (4) travel to one additional training or scientific meeting per year; (5) recruitment costs (up to $3,000 per year) to attract CR Scholars who can excel in and potentially become leaders in clinical research.

4. Research Project Support: Applicants should request an amount of funds, representing typically $25,000 per year per CR Scholar, that will be used to augment his/her research project support during training and/or provide support for a project designed by the CR Scholar. This money, typically $25,000 (and up to $50,000 in exceptional circumstances) per year, can be used for (1) research expenses, such as supplies, equipment, and technical personnel; (2) statistical services including personnel and computer time; and (3) other project infrastructure including relevant data sets.

5. Shared Clinical Research Support Facility: Applicants may request funds, totaling up to $100,000 in the first year and up to $200,000 at full implementation, to set up new specialized shared training facilities that complement existing clinical research infrastructure. These facilities may provide technical training support to aid CR Scholars in developing and managing their research projects. These might include, for example, research design incubators with statistical expertise, a shared pool of study coordinators to work with the CR Scholars, or a curriculum development module.

6. Facilities and Administrative Costs: These costs will be reimbursed at eight percent of modified total direct costs.

7. NIH support beyond the initial five-year project period is not guaranteed and is dependent upon a later decision to issue another RFA, the availability of appropriated funds, and success in any competition for renewed support. In the event that there is no further support, no phase-out funds will be provided. Thus, the applicant institution must have plans in place to provide continued support to remaining trainees in the event that funding from the NIH is not available.

8. Other Income: Awardees may retain royalties and fees for activities such as scholarly writing, service on advisory groups, honoraria from other institutions for lectures or seminars, fees resulting from clinical practice, professional consultation or other comparable activities, provided these activities remain incidental, are not require by the research and research–related activities of this award, and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

All other income and fees, not included in the preceding paragraph as retainable, may not be retained by the career award recipient. Such fees much be assigned to the grantee institution for disposition by any of the following methods:

(a) The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefits must be within the established policies of the grantee institution. (b) The funds may be used for health-related research programs. (c) The funds may be paid to miscellaneous receipts of the U.S Treasury. Checks should be made payable to the Department of Health and Human Services, and forwarded to the Director, Office of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.

Funds budgeted in an NIH-supported research or research training grant for the salaries and/or fringe benefits of individuals, but freed as a result of a K12 award, may not be rebudgeted and may not be used for any other purpose without prior NIH approval.

9. Carryover of Unobligated Balances: The K12 award is subject to Expanded Authorities, with the exception of the authority to carry forward funds from one fiscal year to the next. Such carryover must be approved by the NICHD, Grants Management Branch.

Pre-Award Costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm.

6. Other Submission Requirements

A. Special Reporting Requirements

The K12 award is not subject to the streamlined non-competing application process (SNAP). In general, this means that all reporting of budgetary information and Program progress is provided in greater detail in an annual progress report.

1. Progress Reports: An Annual Progress Report is required. This report should provide information about changes in the Program, a summary report of the evaluation of the Advisory Committee, a description of the efforts to recruit women and ethnic minorities and the research and career progress of each CR Scholar. These Annual Progress Reports will be closely monitored by NIH staff to ensure that the grant is achieving the goals of the Program.

Progress reports are submitted using the Form PHS 2590, which can be obtained at the following website address: http://grants.nih.gov/grants/funding/2590/2590.htm. Forms are also available at most institutional offices of sponsored research. Since the Form PHS 2590 does not apply easily to the K12 grant, adapt the application for continuation to contain the following information:

- Appropriate Face Page A as instructed in the Form PHS 2590.
- A budget page B that provides the salary and fringe benefits for each CR Scholar by name or by position if no individual is filling the position at the time of the application. Provide all other budgetary information (e.g., supplies, travel, technical help) by scholar name or by the position, broken out specifically for each CR Scholar up to the limit.
- A brief description of the Objectives and Goals of the Program.
- A brief summary listing by name, delineating which faculty, mentors, and Advisory Committee members have left the Program and which new individuals have been added or are taking their places. Include for each person his/her degree and department affiliation (or equivalent).
- Biographical sketches of 1) new faculty, 2) new mentors, 3) new MAC members, 3) new CR scholars.
- Progress of Individual CR scholars: A brief paragraph for each CR Scholar describing the research and didactic training experiences completed and ongoing, as well as the specific future plans for satisfying the core requirements of the Program.
- List of publications for each CR scholar resulting from their work in the Program.
- A detailed account of experiences in recruiting individuals from underrepresented groups during the previous funding period (see above).
- Summary information on the Program
- A Report from the MAC that is separately attached summarizing the actions of the MAC during the last year, evaluating the performance of the Program in meeting its objectives and intent, evaluating the effectiveness of recruitment strategies (provide a separate evaluation for minority recruitment), and providing recommendations for improving the Program (e.g., new mentors, changes in core requirements, changes in recruitment strategies etc.)

2. Final Reports: A final progress report, invention statement, and Financial Status Report are required upon termination of an award or relinquishment of an award.

3. Evaluation: In carrying out its stewardship of human resource-related programs, the NICHD may request information essential to an assessment of the effectiveness of this Program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the Program.

B. Special Administrative Requirements

1. Special Leave: Leave to another institution of a CR scholar, including a foreign laboratory, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed three months. For longer periods, prior written approval of NICHD staff is required. To obtain prior approval, the CR scholar must submit a letter to NICHD Program Staff describing the plan, countersigned by his or her department head and the appropriate institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the NICHD and will be granted only in unusual situations. Support from other sources is permissible during the period of leave. Parental leave will be granted consistent with the policies of the NICHD and the grantee institution.

2. Termination: When a grantee institution plans to terminate an award, the NICHD must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination.

3. Change of Institution: The Program cannot be transferred from one institution to another.

4. Change of Program Director: If the Program Director moves to another institution or resigns from the position, support of the award may be continued with NICHD prior approval, provided:

- The current Program Director or the awardee institution has submitted a written request for change of Program Director, countersigned by the appropriate institutional business official, to NICHD Program Staff describing the reasons for the change. The Biographical Sketch of the proposed new Program Director, including a complete listing of active research grant support, is provided. The information in the request establishes that the specific aims of the original peer-reviewed program to be conducted under the direction of the new Program Director will remain unchanged, and that the new Program Director has the appropriate research and administrative expertise to lead the Program.

- The request is submitted far enough in advance of the requested effective date to allow the necessary time for review.

5. Changes of Program: Awards are made to a specific institution for a specific Program under the guidance of a particular Program Director. Changes in any of these parameters require prior approval by NICHD Program Staff. A scientific rationale must be provided for any proposed changes in the aims of the original peer-reviewed Program. The new Program will be evaluated by NICHD Program Staff to ensure that the Program remains within the scope of the original peer-reviewed Program. If the new Program does not satisfy this requirement, the award could be terminated.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds

- Relevance of program priorities

2. Review and Selection Process

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NICHD. Incomplete and/or non-responsive applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NICHD in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by the NIH national advisory councils and boards.

The objective of this Career Development Program is to ensure that highly trained clinical researchers will be available in adequate numbers and in appropriate research areas to enhance the clinical research enterprise for the conduct of clinical investigation. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed Program will have a substantial impact on the pursuit of these goals.

Overall Aims

- Approach/Meeting the Intent of this Initiative
- Institutional Commitment
- Innovation
- Collaborations

Major Program Elements

- Clinical Research Capability and Infrastructure
- Program Leadership/Management
- Multidisciplinary Advisory Committee
- Program Mentors/Team Leaders
- Didactic Core Requirements
- Interactions

Candidate Pool and Recruitment Plans

Evaluation/Tracking

Planning Phase

The scientific review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application. The application need not be strong in all categories to be judged likely to have major scientific and technical merit and thus deserve a high priority score.

(1) Approach/Meeting the Intent of This Initiative: The adequacy of the overall Program strategy from the planning to the full implementation phase in satisfying the intent of this initiative to develop and sustain a high quality Career Development Program that addresses a wide range of clinical disciplines, specialties, and sub-specialties. Does the Program provide excellence in the design and conduct of clinical research and training? Will the Program prepare CR Scholars to become potential leaders in clinical research? Does the Program take maximum advantage of didactic

capabilities, clinical infrastructure, available schools, departments, and disciplines to address the multidisciplinary nature of the program envisioned in this RFA? Does the program include plans for sharing resources outside their institution and for training a national cadre of clinical researchers or only make modest incremental improvements to an already strong program?

(2) Institutional Commitment: Is the institutional leadership committed to this program and its goals? Does the institution provide assurances that the institution intends the Program to be an integral part of its research endeavor, and that clinical research facilities and training opportunities will be a critical part of the environment? Have institutional barriers for clinical research and clinical researchers been adequately addressed? Are tjhere adequate cooperative arrangements between consortium institutions, if applicable, that will ensure that the Program performs effectively as one activity across institutional boundaries? Does this Program cross all departments and integrate all clinical research training programs and clinical research infrastructure elements within the institution, to benefit the entire institution? Does the commitment include specific commitments such as financial support, tuition rebates, or dedicated space? Is there adequate commitment of the institution(s) from the institutional leadership to Department Chairs to protect the time of CR scholars, guarantee 50 to 75 percent professional effort of each CR Scholar, actively engage in the promotion of each CR Scholar's clinical research career, and support the career and tenure process for clinical researchers at the institution?

(3) Innovation: Is the Program original and innovative? Does the Program challenge existing training or career approaches, or address a critical barrier to progress in the field? Does the Program develop or employ novel concepts, approaches, methodologies, tools, or technologies for clinical research education that will lead to the development of the essential skill sets needed to lead clinical studies? Does the program provide strong evidence that the addition of the K12 will provide clinical research career development that would not otherwise be possible?

(4) Quality of Collaborations: The quality of the partnerships between research-intensive institutions and less-research-intensive institutions and/or minority institutions

(5) Clinical Research Capability and Infrastructure: The adequacy of the overall clinical research and training environment and track record of the institution(s) in conducting interactive, multidisciplinary, collaborative, peer-reviewed clinical research (e.g., translational research, Phase I, II, and III therapeutic trials, epidemiological studies, etc.) involving a broad range of clinical disciplines and diseases. The adequacy of the existing infrastructure of the institution(s) (e.g., cores for biostatistics, informatics, data management, research nurses, data managers) supported by NIH (e.g., GCRCs) and other sources. Is the gap analysis complete? Are there sufficient plans to improve and complement the existing infrastructure, and to integrate infrastructure and eliminate overlap in order to support a high quality Career Development Program in clinical research? Are the plans for the Shared Clinical Research Support Facility adequately justified?

(6) Program Leadership/Management: Does the Program Director have the necessary recent clinical research background and administrative qualifications and experience to provide scientific leadership, management, and coordination of a clinical research Career Development Program of this size and complexity? Have the Program Director and co-director(s) committed sufficient time to devote to this Program? Will the Program Director have sufficient authority and credibility in the Institution to work across institutional boundaries?

(7) Multidisciplinary Advisory Committee: Are MAC members sufficiently experienced and representative to oversee this multidisciplinary Career Development Program? Have the MAC members committed sufficient time to meet the needs of the Program? Will the MAC procedures and processes adequately select, monitor, and evaluate the CR Scholars and the overall Program? Are there adequate procedures described for selecting and replacing MAC members? Will the process and review criteria for evaluating the CR Scholars' clinical research projects meet the high scientific standards of an NIH review? Will they be adherent to all applicable Federal rules and regulations?

(8) Program Mentors/Team Leaders: Are the mentors and team leaders who will participate in this Program clearly delineated, do they have the experience, skills, and track record in mentoring necessary to provide CR Scholars with high quality multidisciplinary, team-oriented research training, and do they broadly represent the disciplines, specialties, and subspecialties necessary to make this Program work effectively? Will the mentors commit sufficient time to ensure the success of the Program?

(9) Didactic Core Requirements: Are the didactic requirements sufficient to train CR Scholars to lead, design, and conduct clinical research, and work effectively in collaborative teams? Have the various didactic resources within the institution (e.g., departmental, NIH-supported K30s and GCRCs) been integrated and extended, as necessary (e.g., specialized courses and shared facilities), to effectively meet the needs of the Program? Does the Program have adequate flexibility to accommodate CR Scholars with different levels of experience?

(10) Didactic Core Requirements: Commitment of the applicant to work with other Programs and the NIH as reflected by their proposed ideas to improve performance and outcomes. Commitment to share best practices and to participate in the NIH Roadmap program (http://nihroadmap.nih.gov/) to improve the National clinical research enterprise.

(11) Candidate Pool and Recruitment and Retention Plans: Does the application demonstrate an adequate pool of potential CR scholars, well-defined recruitment and retention strategies, potential sources and numbers of high-quality candidates, and an equitable CR Scholar selection process? Are these processes adequate to achieve and retain a high-quality pool of CR Scholars representative of a broad range of clinical disciplines, specialties, and sub-specialties? Does the Program outline plans for recruitment of CR Scholars from outside the institution? Does the application give evidence of adequate plans to recruit women and members of underrepresented racial/ethnic minority populations?

(12) Evaluation/Tracking: Adequacy of the plans for the MAC and/or other procedures to evaluate the performance of the Program as a whole (e.g., quality of the didactic cores, adequacy of the performance of mentors, adequacy of faculty participation), and to make changes that improve performance and outcomes. Adequacy of the plans to track career outcomes of CR Scholars, including positions held, papers published, grants and awards submitted/obtained, and other relevant information.

(13) Planning Phase: If all milestones are met during the planning phase, will this be sufficient to implement the program after six months?

2.A. Additional Review Criteria:

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research and size of the clinical research base, CR Scholar pool, and mentor pool. The priority score should not be affected by the evaluation of the budget.

Minority Recruitment and Retention Plan: Peer reviewers will separately evaluate the minority recruitment plan after the overall score has been determined. The review panel's evaluation will be included in an administrative note in the summary statement. If the plan for minority recruitment and retention is judged to be unacceptable, funding will be withheld until a revised plan that addresses the deficiencies is received. Staff within the NIH awarding component, with guidance from the appropriate national advisory committee or council, will determine whether amended plans and reports submitted after the initial review are acceptable.

Competing continuation (if applicable) and non-competing applications must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous funding period. Information must be included on successful and unsuccessful recruitment strategies. Recruitment plans and reports should address all efforts to increase the diversity of the trainee pool including those that address: the underrepresentation of individuals from specific racial and ethnic groups that have been shown to be underrepresented either nationally or within the awardee institution; the underrepresentation of individuals with disabilities; or the underrepresentation of individuals who have recently participated in federal programs for individuals from disadvantaged backgrounds. The report should

provide information on all efforts to increase the diversity by describing recruitment efforts and successes at the following stages:

- Students who applied for admission or positions within the department(s) relative to the training grant,
- Students who were offered admission to or a position within the department(s),
- Students actually enrolled in the academic program relevant to the training grant,
- Students who were appointed to the research training grant. For those trainees who were enrolled in the academic program, the report should include information about the duration of research training and whether those trainees finished their training in good standing.

Training in the Responsible Conduct of Research: Every CR Scholar supported by a Multidisciplinary Career Development Program must receive instruction in the responsible conduct of research. (For more information on this provision, see the NIH Guide for Grants and Contracts, Volume 21, Number 43, November 27, 1992, http://grants.nih.gov/grants/guide/notice-files/not92-236.html). Applications must include a description of a program to provide formal or informal instruction in scientific integrity or the responsible conduct of research. Applications without plans for instruction in the responsible conduct of research will be considered incomplete and will be returned to the applicant without review.

Although the NIH does not establish specific curricula or formal requirements, all programs are encouraged to consider instruction in the following areas: conflict of interest, responsible authorship, policies for handling misconduct, data management, data sharing, and policies regarding the use of human and animal subjects. Within the context of training in scientific integrity, it is also beneficial to discuss the relationship and the specific responsibilities of the institution and the predoctoral students appointed to the program.

- Plans must address the subject matter of the instruction, the format of the instruction, the degree of faculty participation, trainee attendance, and the frequency of instruction.
- The rationale for the proposed plan of instruction must be provided.
- Program reports on the type of instruction provided, topics covered, and other relevant information, such as attendance by trainees and faculty participation, must be included in future competing continuation and noncompeting applications. The NIH encourages institutions to provide instruction in the responsible conduct of research to all graduate students, postdoctorates, and research staff regardless of their source of support.

NIH initial review groups will assess the applicant's plans on the basis of the appropriateness of topics, format, amount and nature of faculty participation, and the frequency and duration of instruction. The plan will be discussed after the overall determination of merit, so that the review panel's evaluation of the plan will not be a factor in the determination of the priority score. Plans will be judged as acceptable or unacceptable. The acceptability of the plan will be described in an administrative note on the summary statement. Regardless of the priority score, applications with unacceptable plans will not be funded until the applicant provides a revised, acceptable plan. Staff within the NIH awarding component will judge the acceptability of the revised plan.

Following initial review, the NICHD Advisory Council will also review the applications. The advisory group will consider the assessment of the scientific and educational merit of the research training grant application as well as the initial review group's comments on the recruitment of individuals from underrepresented groups and the plan for instruction in the responsible conduct of research.

2.C. Sharing Research Data
Not applicable.

2.D. Sharing Research Resources
Not applicable.

3. Anticipated Announcement and Award Dates
Not applicable.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm).

A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant organization. The NGA signed by the grants management officer is the authorizing document.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Also Section IV.5. Funding Restrictions.

Once all administrative and programmatic issues have been resolved, the Notice of Grant Award will be generated via e-mail notification from the awarding component to the grantee business official (designated in Item 14 on the Application Face Page). If a grantee is not e-mail enabled, a hard copy of the Notice of Grant Award will be mailed to the business official.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

3. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (http://grants.nih.gov/grants/funding/2590/2590.htm) and financial statements as required in the NIH Grants Policy Statement.

Section VII. Agency Contacts

Applicants are strongly encouraged to contact NIH Program Staff well in advance of the letter of intent submission date to discuss their proposed Career Development Program. There will be a Program website, FAQ's, Listserve, and a pre-submission National meeting (and videocast) to disseminate information about this Program. The date and time of the pre-submission National meeting will be announced via the Listserve and Program website. Applicants are invited to arrange a pre-application consultation with NIH Program Staff. These contacts will assure that the applicants have a thorough understanding of the intent and expectations of this RFA before they engage in the development of an application.

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues.

1. Scientific / Research Contacts:

Joan Davis, M.D., M.P.H.

Program Director, Multidisciplinary Research Programs
Center for Population Research
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8B01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-6515
Email: jd372m@nih.gov

Robert Star, M.D.
Senior Scientific Advisor
National Institute of Diabetes and Digestive and Kidney Diseases
Building 31, Room 9A-19C, MSC 2560
31 Center Drive
Bethesda, MD 20892-2560
Telephone: (301) 594-7717
E-mail: Robert.Star@nih.gov

2. Peer Review Contacts:

Robert Stretch, Ph.D.
Director, Division of Scientific Review
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 5B01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-1485
E-mail: stretch@nih.gov

3. Financial or Grants Management Contacts:

Chris Robey
Grants Management Team Leader
Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A17, MSC 7510
Bethesda, MD 20892-7510
Bethesda, MD 20852 (for express/courier service; non-USPS service)
Telephone: (301) 435-6996
Email: robeyj@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:
Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection:
Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Data and Safety Monitoring Plan:
Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding

studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:
Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Sharing of Model Organisms:
NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:
It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Required Education on the Protection of Human Subject Participants:
NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Human Embryonic Stem Cells (hESC):
Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (http://escr.nih.gov/). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s)to be used in the proposed research. Applications that do

not provide this information will be returned without review.

Public Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Standards for Privacy of Individually Identifiable Health Information:
The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs in NIH Grant Applications or Appendices:
All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.healthypeople.gov.

Authority and Regulations:
This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:
NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50 percent of their time (at least 20 hours per week based on a

40 hour week) for two years to the research. For further information, please see http://www.lrp.nih.gov/.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892